510(k) Summary

APR 2 8 2014

MEDTRONIC Sofamor Danek
ANATOMIC PEEK PTC Cervical Fusion System
March 2014

I. Company:

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. Contact:

Julie Bassett
Regulatory Affairs Program Manager
Telephone: (901) 399-3248
Fax: (901) 346-9738

III. Proposed Proprietary Trade Name: ANATOMIC PEEK PTC Cervical Fusion System

IV. Classification Names: Intervertebral Body Fusion Device (21 CFR 888.3080)

Class: II

Product Code: ODP

V. Description:

The ANATOMIC PEEK PTC Cervical Fusion System consists of PEEK cages of various widths and heights, which can be inserted between two cervical discs to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

The ANATOMIC PEEK PTC Cervical Fusion System will be available in all the same sizes as the predicate system.

VI. Indications for Use:

The ANATOMIC PEEK PTC Cervical Fusion System is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK PTC device is to be used with supplemental fixation. The ANATOMIC PEEK PTC Cervical Fusion System is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open anterior approach.

VII. Summary of the Technological Characteristics:

The ANATOMIC PEEK PTC Cervical Fusion System has the same fundamental technology as the predicate ANATOMIC PEEK Cervical Fusion System. The ANATOMIC PEEK PTC Cervical Fusion System implants (subject devices) and the ANATOMIC PEEK Cervical Fusion System implants (predicate devices), are both made from PEEK material with tantalum markers. In addition, the predicate and subject devices have the same geometry and are designed to contain graft material and facilitate fusion between two vertebral bodies. The only difference between the subject and predicate devices is the subject devices also have a commercially pure titanium (CP Ti) coating.

VIII. Identification of Legally Marketed Devices:

The ANATOMIC PEEK PTC Cervical Fusion System has the same indications for use and fundamental scientific technology as the predicate, ANATOMIC PEEK Cervical Fusion System (K112444, SE 11/15/2011 and K130177, SE 09/23/2013).

An additional predicate, X-Spine's Calix™ PC System (K112036, SE 11/8/2011), is also being used to demonstrate that the titanium coating is not new and currently exists on other legally marketed devices.

IX. Discussion of Non-Clinical Testing:

Testing of the CP Ti coating, which is plasma sprayed, was performed according to FDA's Guidance for FDA Reviewers/Staff, "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements," issued February 2, 2000. The testing was performed according to the applicable ASTM standards listed below:

Coating Microstructure:

- ASTM F1854, Standard test method for stereological evaluation of porous coatings on medical implants

Shear Fatigue Testing:

- ASTM F1160, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/ Metallic Coatings

Static Shear Testing:

- ASTM F1044, Standard test method for shear testing of calcium phosphate coatings and metallic coatings

Tensile Testing:

- ASTM F1147, Standard test method for tension testing of calcium phosphate & metallic coatings

Abrasion Testing:

- ASTM F1978, Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser

In order to demonstrate substantial equivalence to the predicate devices, mechanical testing was conducted. Static compression, dynamic compression, static compression shear, dynamic compression shear fatigue, torsional fatigue, and static torsion testing were performed in accordance with ASTM F2077: Test Methods for Intervertebral Body Fusion Devices. Subsidence testing was performed in accordance with ASTM F2267: Standard Test Method for Measuring Load Induced Subsidence of the Intervertebral Body Fusion Device under Static Axial Compression. Static push-out (expulsion) testing was also performed in accordance with ASTM Draft Standard F04.25.02.02, Static Push-out Test Method for Intervertebral Body Fusion Devices. In addition, wear particulate testing was performed in accordance with ASTM F1877, Standard Practice for Characterization of Particles.

Animal testing was also performed using canines and CP Ti coated coupons.

XI. Conclusion:

Based on the risk analysis, test results, and additional supporting documentation provided in this pre-market notification, Medtronic believes the subject ANATOMIC PEEK PTC Cervical Fusion System is substantially equivalent to the predicate ANATOMIC PEEK Cervical Fusion System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Julie Bassett
Regulatory Affairs Program Manager
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133653
Trade/Device Name: ANATOMIC PEEK PTC Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 26, 2014
Received: March 27, 2014

Dear Ms. Bassett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133653

Device Name

ANATOMIC PEEK PTC Cervical Fusion System

Indications for Use *(Describe)*

The ANATOMIC PEEK PTC Cervical Fusion System is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK PTC device is to be used with supplemental fixation. The ANATOMIC PEEK PTC CERVICAL FUSION SYSTEM is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open anterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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